

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

Website: www.sinobiopharm.com

(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT

**“EVEROLIMUS TABLETS” SUCCEEDED IN PATENT CHALLENGE AND BECAME A
FIRST-TO-MARKET GENERIC DRUG**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**” together with its subsidiaries, the “**Group**”) announces that the “Everolimus Tablets” (Trade name: Qingweishi (晴維時)) developed by the Group has obtained approval for marketing from the National Medical Products Administration of China. Since the implementation of an early resolution mechanism for drug patent disputes (drug patent linking system) in China, it is the first medicine in China to obtain a 12-month exclusivity period under “first generic drug approval + successful patent challenge”. The approved indications are:

- (1) Adult patients with advanced renal cell carcinoma (“**RCC**”) who have previously failed in treatment with sunitinib or sorafenib;
- (2) Adult patients with unresectable, locally advanced or metastatic, well-differentiated (moderately or highly differentiated) progressive pancreatic neuroendocrine tumors (NET);
- (3) Adult patients with unresectable, locally advanced or metastatic, well-differentiated, progressive non-functional gastrointestinal or lung neuroendocrine tumors (NET);
- (4) Adult and pediatric patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not suitable for surgical resection;
- (5) Adult patients with tuberous sclerosis complex-associated renal angiomyolipoma (TSC-AML) that do not require immediate surgical treatment; and

- (6) Postmenopausal women with hormone receptor-positive, epidermal growth factor receptor type 2-negative advanced breast cancer, in combination with exemestane after failure of treatment with letrozole or anastrozole.

Everolimus is a selective inhibitor of the mammalian target of rapamycin (mTOR), which can exert its anti-tumor effects by interfering the growth, differentiation, and metabolism of cancer cells.

Such medicine has shown positive effects in the field of tumor therapy, with definite therapeutic effects on a variety of malignant tumors, and its clinical value has been widely recognized.

- (1) **Good anti-tumor efficacy:** Clinical studies have shown that Everolimus has a more potent anti-tumor effect compared with conventional tyrosine kinase inhibitors. It can be used to treat patients with advanced RCC who have previously failed with sunitinib or sorafenib.
- (2) **Good safety:** Everolimus has less toxic side effects. It has less toxic side effects than sunitinib or sorafenib in antineoplastic therapy.

RCC accounts for approximately 3% of all malignant tumors in adults and represents 90% to 95% of primary malignant renal tumors. It is one of the most common malignancies in the genitourinary system, and in recent years, the incidence and mortality rates of RCC have been increasing all over the world. The number of kidney cancer patients in China is expected to reach 84,000 by 2025. Everolimus is considered to have better efficacy in patients resistant to vascular endothelial growth factor (VEGF)-targeted therapy, bringing new hope to many kidney cancer patients. In 2019, global sales of Everolimus Tablets exceeded US\$2.0 billion.

There is currently no domestic Everolimus Tablets available in the China market, and the branded product is expensive with limitations on medical insurance reimbursement. The Group has overcome the technical hurdles of developing Everolimus, and has successfully challenged the patent of the branded product and obtained a 12-month exclusivity period. The launch of Qingweishi as a first-to-market generic drug can significantly reduce the medication burden on patients and benefit more tumor patients.

By order of the Board
Sino Biopharmaceutical Limited
Tse, Theresa Y Y
Chairwoman

Hong Kong, 3 January 2024

As at the date of this announcement, the Board of the Company comprises seven executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, Mr. Tian Zhoushan and Ms. Li Mingqin and five independent non-executive directors, namely Mr. Lu Zhengfei, Mr. Li Dakui, Ms. Lu Hong, Mr. Zhang Lu Fu and Dr. Li Kwok Tung Donald.